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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/786,435	02/24/2004	Emmett Clemente	30610/30022	4917

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EXAMINER	
WILLIAMS, LEONARD M	
ART UNIT	**PAPER NUMBER**
1617	

DATE MAILED: 08/11/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/786,435	CLEMENTE ET AL.	
	Examiner	Art Unit	
	Leonard M. Williams	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 February 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-14* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-14* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Detailed Action

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Anaebonam et al. (US Patent No. 5763449) in view of Santos et al. (US 2003/0118654 A1).

Anaebonam et al. teach, in the abstract, a liquid pharmaceutical composition comprising a pharmaceutically effective amount of a bitter tasting drug dissolved or dispersed in an aqueous medium comprising 5-30 weight % polyvinylpyrrolidone, 45-55 weight % of a C3-C6 polyol, 0.01-0.5 weight % ammonium glycyrrhizinate and one or more flavorants. The liquid composition is transparent. In col. 2 lines 55-65, Anaebonam et al. teach that prednisolone sodium phosphate (and prednisolone itself) is a bitter tasting drug contemplated for formulation in the liquid pharmaceutical composition. In col. 4 line 20 to col. 5 line 40, Anaebonam et al. teach that the bitter-tasting drugs are to be present in amounts of about 0.1to 10 weight percent, preferably about 0.5-5 weight percent. The amount of polyvinylpyrrolidone to be present is from about 5-30 weight percent and preferably about 7-15 weight percent. The C3-C6 polyols are to be present in about 45-55 weight percent and include propylene glycol, glycerin, threose, sorbitol, sorbose, glucose, mannose, galactose, xylose, fructose, malitol, etc... The C3-C6 polyol can be formulated to have a C3 to C6 ratio of from 1:4 to 3:5 or in another preferred embodiment polyols other than the C6 polyol constitute less than about 5 weight percent of the total composition. The amount of ammonium glycyrrhizinate present is about 0.01-0.5 weight percent.

In col. 5 lines 30 to 35, Anaebonam et al. teach that the final composition has a final pH value of about 2 to about 8 and preferably about 3 to about 5.

Anaebonam et al. do not teach C3-C6 polyols in concentrations of about 60 to about 75 weight percent including more than 55 weight percent of a non-reducing di- or tri- saccharide. Nor does Anaebonam et al. teach the use of sodium or potassium sorbate and/or benzyl alcohol as a preservative.

Santos et al. teach on page 1 paragraph 0011, a pharmaceutical liquid composition comprising about 0.1 to about 10 weight percent of at least one bitter-tasting drug, about 0.5 to about 10 weight percent polyvinyl pyrrolidone and/or copolyvidone, about 0.05 to about 10 weight percent polyethylene glycol of MW 4000-6000, about 30-90% of a sweetening composition, about 0 to about 0.4% of a viscosity-building agent, about 0-20% of a polyhydric alcohol, and 0.1-0.5% of a flavoring agent. The liquid composition would be adjusted to a pH between 2.5-8.

On page 3 paragraph 0026 Santos et al disclose that the water-soluble sweetening composition can include sweetening agents such as glucose, fructose, sucrose, maltose, xylose etc... in amounts of about 20-95%.

On page 9 Table 16 Santos et al. disclose a dextromethorphan hydrobromide syrup comprising dextromethorphan hydrobromide of 0.3g, sucrose 60g, povidone (polyvinylpyrrolidone) 2.5g, polyethylene glycol 6000 0.25g, sodium benzoate 0.2g, sucralose, 0.2g, saccharin sodium 0.13g, flavoring 0.3g, citric acid 0.64g, sodium citrate dihydrate 0.64g, and purified water q.s to 100ml.

It would have been obvious to one of ordinary skill in the art that at the time the invention was made to use the non-reducing sugar-sucrose of Santos et al. in quantities greater than 55 weight percent in combination with other C3-C6 polyols, in the liquid

compositions of Anaebonam et al. as both Anaebonam et al. and Santos et al. contemplate the use of di- and tri-sacchride compounds in their respective formulations and for the same purpose (masking of bitter tasting drugs). One would have been motivated to use sucrose in such high amounts in order to better mask the bitter-tasting drugs with the sweetness of the sucrose, additionally as sucrose is a non-reducing sugar it would be expected to have greater stability and less reactivity in liquid preparations.

It would have been obvious to one of ordinary skill in the art at the time the invention was made that any pharmaceutically acceptable preservative agents could be used in the formulation of the Anaebonam et al. and Santos et al. compositions. Anaebonam et al. and Santos et al. both use sodium benzoate as a preservative agent thus obviating the use of a preservative agent in their formulation. The current application does not indicate that the preservative agents claimed are of particular importance.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leonard M Williams whose telephone number is 571-272-0685. The examiner can normally be reached on MF 9-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 571-272-0629. The fax phone

number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

LMW

SREENI PADMANABHAN
SUPERVISORY PATENT EXAMINER